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REPORT TO CONGRESS:

MONITORING CHANGES IN USE OF, ACCESS TO, AND APPROPRIATENESS OF PART B MEDICARE SERVICES

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Acknowledgment

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Chapter I

Background and Executive Summary

This is the first annual report under section 6102(a) of the Omnibus Budget Reconciliation Act of 1989 (OBRA 89: P.L. 101-239) which added section 1848(g)(7) to the Social Security Act. This addition to the law requires the Secretary of the Department of Health and Human Services to monitor:

> "(i) changes in utilization of and access to services furnished under [Part B] within geographic, population, and service related categories,
>
> (ii) possible sources of inappropriate utilization of services furnished under [Part B] which contribute to the overall level of expenditures under [Part B], and
>
> (iii) factors underlying these changes and their interrelationships."

The Secretary is to study and report annually to Congress on the changes described in paragraph (i) and include in the report "an examination of the factors (including factors relating to different services and specific categories and groups of services and geographic and demographic variations in utilization) which may contribute to such changes."

Both the legislative context and the statement of managers make clear this requirement is primarily intended to evaluate the impact on utilization, access, and appropriateness of the changes in Medicare physician payments mandated by OBRA 89. These changes include the Medicare Fee Schedule (MFS), the Medicare Volume Performance Standards (MVPS), and limitations on balance billing of beneficiaries for Medicare services.

This report describes the research and monitoring systems that the Health Care Financing Administration (HCFA) is establishing, as a foundation for future annual reports. Over the last few years, HCFA has designed and is now putting in place a diverse, yet carefully integral, set of data acquisition and information management systems that will better support ongoing monitoring of the impacts of program changes on utilization, access, appropriateness, and outcomes of care. Table I-1 shows how these new systems will affect the timeliness and scope of evaluative data.

In addition, HCFA is actively pursuing research to help interpret the data resulting from these systems. The report does not provide detailed reports from the research, which is not complete, or data from the systems, which are not yet fully operational.

Organization of the Report

This report comprises six chapters. This first chapter provides the context and legislative history for the report, and then provides an Executive Summary of its discussions and findings. The second chapter provides an overview and timeframe for the development of the data systems related to Part B Medicare services. This organization as a separate chapter is intended to be clear and convenient for the reader, but the reader should keep in mind that (a) each of these data systems will also be useful for studies described in each of the subsequent chapters, and (b) studies in each of the three areas will shed light on the other areas.

Following Chapter II on data systems, there are three chapters (III, IV, and V) describing approaches to studies of utilization, access, and appropriateness. Each of these chapters also references again in greater detail the data systems most useful for studying the issues described in that chapter. (The Executive Summary also integrates to some extent the discussion of data systems with approaches to understanding utilization, access, and appropriateness.) A final chapter (Chapter VI) discusses an added dimension of monitoring: outcomes analysis. It concludes with a discussion of the challenge for fully integrating data systems for ongoing monitoring and timely policy development purposes.

Summary of Findings

This report can be viewed as a type of longer-range "blueprint" or framework for organizing and implementing a strategy for monitoring changes in Medicare Part B services. It outlines a number of impressive achievements either underway or planned, and the forward-looking research agenda that may help clarify factors contributing to such changes.

At the same time, it points up the major conceptual obstacles inherent in defining, identifying, and measuring utilization, access, and appropriateness of medical services. Second, it attempts to develop realistic timeframes for being responsive to the mandates of Congress; nevertheless, the scale and sheer complexity of the Part B program under Medicare ensure that these tasks will be daunting and present ongoing challenges.

Data

Data are pivotal in identifying and monitoring program impacts and change. While significant strides have been achieved over the last 10 years, more comprehensive and more reliable data on Part B is expected to be available in the future.

HCFA's data systems developed from a payment system that historically has been extremely diverse; as standardized national rules and computer systems reduce variation among Medicare's Part B carriers, data -- particularly claims-based data -- become increasingly reliable and lag-times decrease. Steps contributing to this improvement include:

(1) Standardized Definitions. In September 1990 the Secretary delivered to Congress and published a model fee schedule[1] that describes how HCFA will standardize definitions for

Part B claims data.

(2) Unique Physician Identification Number (UPIN). HCFA has assigned a UPIN to every physician in the United States for whom it has a record of a Medicare billed service since 1987. Current plans call for the UPIN to become part of all electronic bill records during 1991; when implemented, this could allow improved analysis of changes in services provided by individual physicians, some of which was not possible in the past.

(3) Direct Submission of Unassigned Claims. OBRA 89 requires that, effective September 1, 1990, physicians submit all claims directly to Medicare carriers, including those claims on which they did not accept assignment. HCFA expects direct submission to improve the timeliness and accuracy of estimates of changes in utilization.

(4) National Claims History (NCH) system. The NCH system is a national archive of all Medicare claims processed through the Common Working File (CWF), which became fully operational in early 1991. The CWF and NCH are major innovations in the way HCFA authorizes payments and captures claims data for program development and evaluation. These innovations could:

- Increase the timeliness of claims information for utilization tracking, and
- Improve data quality by standardizing data acquisition and analytic files, and by increasing data quality

review.

The NCH system is a product of HCFA's larger Project to Redesign Information Systems Management (PRISM), which is attempting to create tools to substantially improve access to claims, beneficiary, and provider data, thus enhancing HCFA's longer-term ability to analyze and interpret trends.

Other data systems, either proposed or under development, promise to further enhance these abilities. Briefly, these include:

(1) The Current Beneficiary Survey (CBS). The CBS is a proposed project, and planned as an ongoing panel survey of the Medicare beneficiaries including the aged and disabled residing in the community and in institutions. The CBS could substantially improve HCFA's ability to describe costs, expenditures and sources of payment for health care; monitor effects of Medicare program changes; and assess program effects -- such as changes in access to care -- on beneficiaries.

(2) Peer Review Organization (PRO) Data. PROs use both billing data, which are currently available but require further development for analysis, and an expanded data base under development (including the Uniform Clinical Data Set or UCDS) that contains a broad range of clinical information from hospital and other patient records. The UCDS will collect a standard set of data about each hospitalization, subject that data to an expert system, and provide to

physician reviewers a case summary reflecting specific areas under question. This data system could allow a change from traditional individual case review to broader issues of clinical concern about the appropriateness of the medical care being provided (see Chapter V for more discussion on this point).

(3) Medicare Beneficiary Health Status Registry ("Registry"). The Registry is a proposed longitudinal data base containing information formed by joining health status information obtained by a panel survey of beneficiaries and then linked with HCFA's administrative files. The survey would gather previously unavailable information regarding the health status of approximately 2 percent of the elderly as they enter the Medicare program and at 2 and 5 year intervals thereafter. By enrolling successive cohorts over many years, changes in the health and utilization of new entering groups could be monitored over time. Repeated survey contacts with the same individuals could allow improved monitoring of the progression of health and disease, the effectiveness of specific health interventions, and the overall relationship between the Medicare program and health status of beneficiaries. The Registry is currently being developed, but it will not be known for several years whether the Registry will be able to gather health status information of sufficient accuracy to satisfy the purpose for which it is being developed, or

if so, at what cost. Therefore, no final decision has yet been made to implement the Health Status Registry.

Utilization

To monitor changes in utilization of services under Medicare (Chapter III), HCFA is building upon its solutions to challenging data problems and supporting research to clarify the forces behind growth in utilization.

There are obvious and important questions to be addressed concerning the impact of the OBRA 89 changes on utilization of services; these include:

- What will happen to overall volume of services?
- What will happen to volume of specific types of services and the volume and mix of services across areas?
- What will happen to utilization of services in the aggregate and for specific types of services, for special population groups (e.g., more elderly beneficiaries, disabled or End Stage Renal Disease (ESRD) beneficiaries, minorities)?
- Will the overall levels in use (and cost) of services increase, decrease, or remain unchanged as the statutory changes are implemented?

Beyond observing these specific but straightforward statistical trends, there are a set of longer-range research issues, such as:

- To what extent does procedure growth reflect demand factors such as patient needs and preferences, and to what extent does growth reflect supply factors such as physician availability and presence of facilities?
- How do physicians and patients change their behavior, both in the short and in the long run, in response to changes in payments and liabilities? For example, will beneficiaries' use of services change when their out-of-pocket costs are reduced by balance billing limits?
- What are the growth cycles of different kinds of procedures? Do some procedures have a self-limited cycle of growth (e.g., are used only in limited, well-defined circumstances)?
- To what extent is growth in services medically appropriate? Increases in levels of services may be appropriate, for example, if they represent new and clearly beneficial technology; increases could also represent proliferation of services whose effectiveness is uncertain. (This question is primarily addressed in Chapters IV and V, which consider access and appropriateness.)

Despite the improvements in information systems, interpreting growth patterns will remain formidable for several years. For example, there is still uncertainty as to the extent to which apparent differences in growth of utilization among localities reflect data problems.

Access

To monitor changes in access to care for Medicare beneficiaries (Chapter IV), HCFA will study approaches that might better measure both (a) barriers that beneficiaries encounter when they use services, and (b) the extent to which beneficiaries receive medically necessary care.

A major source of data on beneficiaries reporting barriers could be the proposed CBS. Information providing clues to patterns of medically-necessary services will come primarily from analysis of claims data. Trend data from CBS could be available as early as 1993 (depending upon survey approval), and improved trend data from analysis of claims may be available as early as 1994.

The receipt of necessary care could be studied through a variety of analyses of claims data, the use of the proposed Medicare Registry, and through longer-term research. For example, HCFA's Research Center at Project HOPE recently recommended that observing disparities in utilization rates for various groups of beneficiaries at a point in time -- whether across geographic areas or across beneficiary characteristics such as race -- could be indicative of lack of access for the lower use groups as well as inappropriate overuse for the higher use groups. Information collected initially and monitored longitudinally by the proposed Registry, when linked with utilization data, could permit increased understanding of the distribution of underlying differences in health status and risk factors for health conditions -- allowing a more direct measurement of need for health services. This could help identify possible groups with unequal access to care.

Finally, HCFA's Office of Research and Demonstrations also is readying a cooperative agreement solicitation directed at improving conceptual foundations, measurement, and understanding of barriers to access to care. This solicitation, as well as ongoing, longer-term research both within HCFA and the Agency for Health Care Policy and Research (AHCPR), could develop tools for measuring rates of receipt of medically necessary services.

Ideally, monitoring access would involve not only measuring but also analyzing changes. The goal would be to link any improvement or deterioration in access to specific program changes such as alterations in payment or beneficiary liability. This goal is extremely ambitious and, considering the number of Medicare program and environmental changes that will occur over the next few years, may not be achievable.

Any approach to monitoring access must complement the monitoring of appropriateness described below because it could identify appropriate care that was not received. The appropriateness strategy, on the other hand, would principally address the appropriateness of care that is received.

Appropriateness

The Medicare program approaches the question of appropriateness in two ways, through:

- National standards as to what services will be paid for ("covered") by the program, and
- More local programs of pre-certification, pre-payment screening, and post-service review.

Even though there are a few national rules governing what services will be reviewed under the latter activities, HCFA uses the professional judgment of local reviewers to make pre-certification or post-service determinations of appropriateness. Recently, however, a growing number of critics has pointed out that many accepted community practices have very limited scientific foundation, and judgments as to what is appropriate are usually difficult to justify through reference to the best scientific literature.

Monitoring of changes in appropriateness of care (Chapter V) requires (a) developing guidelines as to what care is appropriate, and (b) measuring the care provided to Medicare beneficiaries against these guidelines. Practice guidelines are currently being developed through AHCPR. To the extent applicable to the Medicare population, these guidelines could be applied -- with other available standards -- through new data and analysis systems (such as the UCDS) being planned and "pilot" tested by HCFA's Health Standards and Quality Bureau (HSQB).

Through PROs, HSQB is responsible for monitoring the appropriateness of care delivered to Medicare beneficiaries. HSQB is engaged in making the PRO program more systematic in its assessment of the quality through a combination of automated clinical patient data and an expert system of electronic clinical logic. Initially, the automated data might be limited to that obtained from inpatient hospital medical records and the expert system will rest on consensus-based algorithms. In the longer term, the data required could include information from all care settings and the expert system could evolve into a real-time experience-based decision support tool founded on epidemiologic analysis of the experience of physicians treating Medicare patients.

Over the next 3 years, HSQB plans to begin using newly automated screening systems; these, in turn, could feed directly into a ongoing tracking system. The validity of these screens, however, requires continual refinement through epidemiologic studies and case review, the value of which are as yet indeterminate. Additionally, this strategy will take a minimum of several more years to yield trend data. But HCFA believes that counts derived from current systems for review of appropriateness provide little information on changes in appropriateness of care. As with access and utilization, HCFA will attempt to link trends in appropriateness with specific program changes, but similar difficulties persist in this area as well.

Outcomes

Chapter VI describes another long-term dimension of monitoring: outcomes analysis. This final chapter then examines some important differences between monitoring and more traditional program evaluation. Although monitoring is a more powerful and useful approach, analysis will be very complex and associating changes in monitored trends with specific program changes may prove impossible.

Chapter VI concludes with a discussion of the challenge of integrating information systems for future analysis and monitoring. The data systems described primarily in Chapter II, but in greater detail in Chapters III, IV, and V, have been developed for operational purposes, but may have broader application than the specific topics of the chapters in which they are discussed. For example, claims data may identify potential access and appropriateness issues, as well as provide some outcomes. The CBS could provide limited information on utilization not available from claims data.

Chapter VI ends with a brief description of the ways in which the monitoring processes can bring HCFA closer to a process of continuous quality improvement.

Attributing Causation: Limitations

An important goal of the analyses mandated by OBRA 89 is clearly determining the effects of program changes. It is an issue and theme throughout each of the chapters of this report. Attributing changes in utilization, access, or appropriateness to specific program changes will be difficult, though, for at least two reasons:

(1) Timeframes. Although it is easy to identify the moment when a Medicare program change becomes operational, identifying the time at which it affects patient and physician behavior may prove much more difficult. For example, many of the payment changes under the MFS actually started with "overpriced procedure" cuts in OBRA 87 and OBRA 88 and will be phased in during a transition period extending into the mid-1990s. Conversely, physicians may respond to expected changes rather than reacting on the day changes occur; in extreme cases, the actual change may fall short of the expectation and the response to the actual change may be the reverse of that expected.

(2) Multiple Concurrent Changes. The world of Part B services is changing in many ways at once, and disentangling causes will be, at best, very difficult. Although changes will be different for different groups of physicians and payments, making some multivariate analysis possible, a very large number of possibly causal events will be occurring at roughly the same time, including:

- Within Medicare, the MFS, MVPS, and balance-billing limits;
- In the general health care sector, changes in the

relations of physicians to hospitals, shifts in the policies of other insurers, and developments in health care technology;

- In the general economy, changes in the ability of beneficiaries to pay out-of-pocket costs and of physicians to do without Medicare income.

Thus, despite the importance of each of the issues described and discussed in the course of this first Report to Congress, causal conclusions can be ambiguous at best.

Table I-1

Change in Availability of Program Data: Calendar Years 1990-95

Information system	Typical lag (months)		Routine/ special study in 1990	In place
	1990	1995		
Part B utilization	10-22	5-8	routine	1991/2
Access to care	24-36	6-10	special	1993/4
Appropriateness of care	48	4-8	special	1994/5
Outcomes	12-36	6-12	largely special studies	1994/5

Chapter II

Data Systems For Monitoring Changes: Present and Future

Data are pivotal in identifying and monitoring program impacts and change. In laying out a conceptual framework for identifying and tracking changes in utilization, access, and appropriateness, it is logical to begin with an overview of Medicare's information capabilities -- both current and future.

While significant strides have been achieved over the last 10 years, more comprehensive and more reliable data on Part B are expected to be available in the future. This chapter begins with a description of Part B claims files and then describes more specific data systems that might be used to monitor changes in utilization, access, and appropriateness of care.

Part B Claims

Data on Part B physician services historically have come from claims submitted either by patients or by physicians; as of September 1, 1990, physicians and other providers must submit all bills directly to HCFA contractors. This change could help improve the accuracy and timeliness of the data.

Contents

The electronic record created from each bill includes:

(1) the provider number (a number that is assigned by the carrier and may cover several physicians in a practice or only parts of the total practice of one or more physicians); in 1991 the UPIN (see below) will be added;

(2) the physician's specialty;

(3) the service provided (coded in HCFA's Common Procedure Coding System (HCPCS), which is an expansion of the American Medical Association's Current Procedural Terminology (CPT-4)),

(4) the diagnostic code,

(5) the date of service,

(6) the site of service (office, hospital, nursing home, etc.) and

(7) the charge for each service.

Since 1989, three different systems have reported data from Part B claims. They are Bill Payment Records, Part B Medicare Annual Data or BMAD, and National Claims History; each are discussed in turn below.

Bill Payment Records

Until the implementation of the CWF, carriers* created and submitted payment records for noninstitutional Part B services.

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* Carriers are insurance companies that process Medicare Part B claims; a carrier serves one or more States or part of a larger State.

While the bill payment record system is the longest-established of the Part B data systems (dating from 1972), it is also the most limited:

(1) Completeness. The payment record system creates files after payment is complete and operates outside of the claims processing system. There have been significant reporting shortfalls in the data, due to both missing and incorrect submissions from some carriers. There are also some duplicate bills. In all cases, claims applied entirely to the deductible are absent because there was no payment.

(2) Timeliness. Bill payment data enter the system only after the bill is paid, often long after the service.

(3) Detail. A payment record is created for each provider on a single claim. Each record is a summary of payments made on a claim for that physician's services. The place and type of service are reported for the service with the largest charge on the claim. In addition, no procedure code is reported on the payment record.

Bill payment records have become less used as other systems have improved.

Part B Medicare Annual Data

The BMAD system consists of four files: (a) a Procedure file that contains frequency counts and average allowed charges for all procedures in all localities, (b) a Beneficiary file that contains all claims for services to a 5 percent sample of beneficiaries, (c) a Provider file that contains all claims for services by a 5 percent sample of providers, and (d) a Prevailing Charge/Pricing file that contains prevailing charges/fee schedules for all procedures in all localities.

BMAD files through 1985 were seriously flawed, but files for 1986 - 1989 provide better information and are more carefully monitored than bill payment record data. Through 1990, BMAD files continued to be created and submitted to HCFA after the end of each year by individual carriers, which extracted the files from the carriers claims history files. Each processing site developed these extraction systems independently, and there are inconsistencies among the processing sites in the definitions used in developing the files.

The resulting files currently have several limitations including:

(1) Completeness. The files contain only claims submitted within 3 months after the close of the calendar year when carriers create the files they submit to HCFA.

(2) Timeliness. BMAD files for a year have typically become available 10-12 months after the end of the year.

(3) Carrier Problems. Carriers make errors in creating the files that go into BMAD; each year the data from some carriers have significant numbers of omissions or duplicate claims.

(4) Provider File. The BMAD provider file consists of all claims from a 5 percent sample of providers. Provider numbers are assigned independently by each processing site; provider numbers are assigned for billing purposes and may change. Further, each processing site draws the sample, and there is variation in sampling procedures among the carriers.

(5) Coding Practices. Carriers use local codes, and even standard codes (e.g., "modifiers" that indicate partial or increased services) are not applied uniformly. This problem should be alleviated to a considerable degree following standardization of policies stemming from Physician Payment Reform.

More generally, the issues of completeness, timeliness, and carrier practices should improve in the next few years. This is in great part due to BMAD files being constructed as subsets from the NCH file beginning in 1991.

National Claims History System

The NCH system is a national archive of all claims processed through the CWF. The CWF is a decentralized Medicare claims validation and benefit authorization process. Each CWF site edits claims and authorizes payments. When the CWF site authorizes payment, an authorization notice goes to (a) the fiscal agent to enable payment, and (b) to HCFA for inclusion in the NCH system.

Because CWF forwards data to NCH when a claim is approved for payment, data may become available for analysis in a much more timely fashion than the previous BMAD reporting process. Current BMAD data are processed annually so that the data file for a year is available for analysis about a year after the year is over. Thus, data from the second quarter of 1989 now become available for analysis about the end of 1990, 18-21 months later. After an initial implementation phase of the next few years, when the NCH file is operating smoothly, the data from the second quarter of 1992 would be expected to be available for analysis during the fourth quarter of 1992 -- between 3 and 9 months later. Thus, the data lag eventually could decrease substantially, especially for the early months of a year.

Nevertheless, the NCH system has certain limitations:

- 1991 will be the first full year of data. It is realistic to expect that a number of data reporting issues will emerge in this first year.
- The file is very large (about 500,000,000 or 500 million claims a year). By comparison, Part A claims for hospital admissions total only about 11 million per year. The sheer magnitude of this file will make custom analyses difficult.

The 1991 BMAD procedure and beneficiary files will be constructed continuously at HCFA from the CWF, and the provider file sample will be drawn continuously when the UPIN is fully implemented. Until UPIN is fully implemented, a special sampling method can be used to accommodate provider numbers assigned by carriers. Once the UPIN is fully implemented, provider sampling will become consistent.

Complete (100 Percent) Claims Files

Two HCFA grantees have obtained complete files of claims for several States for several years in order to pursue analytic studies. Although these files represent only a few States and findings are not always generalizable for national policy purposes, they can provide the basis for special projects.

Other Data Improvements

Listed below are several improvements that are being implemented roughly parallel with CWF changes; these changes include:

(1) UPINs (unique physician identification numbers), which will permit linkage of services to individual physicians (in contrast to the provider numbers, which are assigned to practices).

(2) Standardization, of a variety of coding practices (for example, local codes will be largely discontinued, use of modifiers will be standardized, and the services included in the surgical global fee will be standardized). In September 1990, the Secretary delivered to Congress and

published a model fee schedule[1] that describes how HCFA will standardize definitions for Part B claims data. These standardizations could make comparisons more reliable across States and carriers and, ultimately, over time.

The Current Beneficiary Survey

The CBS is a proposed project, and planned as an ongoing panel survey of the Medicare beneficiaries including the aged and disabled residing in the community and in institutions.

Goals

The CBS could be used to:

- support the development of the National Health Accounts,
- project and monitor the integrity of the Trust Fund,
- describe costs, expenditures and sources of payment for health care,
- monitor effects of Medicare program changes,
- assess program effects on beneficiaries,
- simulate the potential implications of legislative, regulatory and program changes, and
- conduct epidemiological studies associated with aging and institutionalization.

The CBS could produce a continuous data base, whose strength is the long term nature of the panel study and the flexible design. HCFA administrative data (including claims data) would be linked to the survey data for analysis, producing data that are both richer and subject to cross-checks for validity.

Sample

The universe for the CBS would be current Medicare beneficiaries living in the United States and Puerto Rico. The total sample size would be 12,000. Special populations, such as the disabled, the elderly in nursing homes or institutions, and the extreme elderly would be oversampled. The sampling frame would be the Health Insurance Master File, but for each sampled person who is in a nursing home, a cluster or network of additional residents in the same institution would be selected.

Data collection for the CBS could be continuous. Sample persons would be interviewed every 4 months for several years. The longitudinal nature of the panel survey provides the opportunity to observe changes in use with changes in coverage and health status. This also allows observation of processes that occur over time, such as institutionalization or the spending down of assets.

Content

The proposed CBS would have both core questions and supplements.

Core Items. The core would focus on beneficiaries' (community based and institutional) patterns of use, expenditures and cost over time, sources of coverage and payment, demographic characteristics, health and functional status and work history. The core items of the CBS which would be asked each round include:

(a) Detailed questions about the respondent's health care utilization since the last interview, including hospital stays, hospital outpatient care, physician visits, home health care, drugs, durable medical equipment, and other utilization categories;

(b) The reasons for each utilization episode;

(c) Expenditures associated with each episode and sources of payment, including out-of-pocket costs; and

(d) Insurance coverage.

Supplements. In addition to the core items, the CBS could use supplements. These would expand the scope and content of the survey without affecting the integrity of the core questionnaire. Supplements would enable the CBS to be responsive to legislative and programmatic issues and proposed changes in a rapid and flexible manner. These supplements could be asked either annually or on a one-time basis.

(a) The CBS is proposed to field the following supplements annually:

  - Access component of the core questionnaire (see below),
  - Health Status and Functioning Supplement,

- Income and Assets Supplement,
- Cognitive Functioning and Mental Health Supplements.

(b) Supplements that are proposed to be fielded on a one-time basis include:

- Informal Support,
- Influenza Vaccinations, and
- Preventive Services.

(c) Supplements could also be used to address:

- The effect of working and work history on the need for health services and on coverage;
- The effect of income and wealth on health insurance coverage and on program eligibility under various legislative proposals;
- The relationship of hospitalization to post-hospital outcomes of care, cost, and utilization;
- The state of beneficiary knowledge about developments in the program and the effects of HCFA's communication for various types of beneficiaries; and
- Beneficiaries' perceptions of physician services provided under Medicare; e.g., the Medicare participating physician program and assignment issues.

Schedule. CBS is proposed to begin a pilot testing of data collection in September 1991. A first round of the survey could begin a year later, and would consist of the core questionnaire, excluding questions on cost and total charges but including the access series of questions. This first round could collect data from September 1, 1992 to December 31, 1992 and would establish the respondent reference period for all subsequent rounds.

In January 1993 the second round could be scheduled to begin if the first round is approved and is implemented as planned. This round initiates the core of the household questionnaire (including the cost and charge series) and the income and assets supplement.

Availability of Collected Data. CBS is designed as a computer-assisted survey in which responses will be entered directly into the computer by the interviewer; responses in one cycle of the interview become questions in the next cycle as interviewers seek further information about care reported in earlier cycles. Thus, information from a cycle must be processed by the beginning of the next cycle, making responses theoretically available for analysis no more than 4-6 months after an interview, or not more than 8 months after care is provided. Data available so rapidly will not, however, be final because of errors. These will have to be caught and corrected during follow-up in the next cycle.

Peer Review Organization Data

PROs are independently contracted organizations created to monitor and assure quality of care for Medicare beneficiaries. PROs use both billing data, which are currently available but require further development for analysis, and an expanded data base under development (including the UCDS) that contains a broad range of clinical information from hospital and other patient records.

Uniform Clinical Data Set. The UCDS is a new data collection and case finding system that has been developed by HCFA's HSQB. What UCDS does is to collect a standard set of data about each hospitalization, subject that data to an expert system, and provide to the physician reviewer a case summary that reflects the specific areas which are being questioned and highlights the issues that need to be addressed.

This data system will allow a change from traditional PRO review, which relates more to the individual case and only in a general way to the broader issues of clinical concern about the appropriateness of the medical care being provided (see Chapter V for more discussion on this point).

The goal of a UCDS-based approach is to select cases for physician review in each State by identical standards, thus eliminating the differences in PRO review results attributable to individual nurse judgment and/or locally developed screening criteria. Further, the data being collected can be matched to other Medicare data files to enable detailed longitudinal analyses to be performed. This could yield information about the effectiveness of different and competing medical interventions.

Goals. The UCDS is designed to be interactive and usable by a trained abstractor to collect data from a patient's medical record utilizing desktop or portable computer hardware. In choosing the data elements for collection in UCDS, two primary guidelines will be used.

First, all needed elements for running through clinical algorithms must be identified and defined. Additional elements that will be necessary for an epidemiologic/longitudinal database also must be identified and included. Data describing diagnostic and therapeutic interventions, intermediate and final adverse outcomes, patient severity of illness at admission, and patent status will also be included.

Second, the total number of elements collected for each case must be within practical limits of cost and data storage/processing. A generic, rather than condition-specific, approach will be taken. That is, the elements eligible for collection will not vary according to the type of case. Instead, what will be included are a combination of the likeliest data elements to appear in the medical record plus less frequently seen elements, but important for particular types of cases. Although the UCDS will include 1,600 elements, the number of data items collected for each case will likely vary depending upon the medical condition. On average, 250-300 elements will be collected per case; rarely will a case involve more than 600 elements.

Sample and Content. The PRO system now monitors a 3 percent random sample of Medicare discharges from all PPS hospitals and Maryland hospitals reviewed by the PROs. The UCDS sample proposed would expand the random sample to 10 percent of all beneficiaries. The data collected from the PRO sample include both risk factors and in-hospital outcomes of care. Data in the following categories would be collected under the UCDS approach:

- Administrative information;
- Sociodemographic data.
- Admission medication history;
- History of permanent anatomic changes;
- History and physical, including chronic diseases;
- Laboratory findings, for chemistry and blood gases, hematology/urinalysis, microbiology, cytology/histology;
- Selected diagnostic tests;
- Endoscopic procedures;
- Operative episodes;
- Noninvasive treatment interventions;
- Hospital course (e.g., special care unit stays); and
- Patient discharge status.

A number of items also are collected with reference to specific periods of the hospital stay. For example, data describing the condition of the patient at admission are those collected within the first 24 hours of the stay or preoperatively, if surgery was performed in the first 24 hours. For certain lab tests (e.g., cardiac enzymes), the time window is within 48 hours of admission.

Timing. Under the most optimistic scenario, it will be 3 years (1994) before the UCDS data base will include uniform, nationwide data.

In early to mid-calendar year of 1991, HCFA will modify the contracts of seven PROs to begin implementation of phase I of the transition to different set of PRO functions. These seven PROs will be capturing, in automated formats, complete clinical information for a 6 percent sample of hospital admissions in their respective States. The automated expert system will identify cases needing further physician review. This process will become the basis for PRO review. Depending upon these "pilot" results, other PRO contracts might be modified to conduct review in this way.

Simultaneously, HCFA is developing a prototype data management and analysis infrastructure -- including both hardware and epidemiologic software -- for PROs to use in performing the more sophisticated analyses of variations in use and outcome. All of the clinical data and the automated patient information from the hospital record will be retained and merged with other HCFA data for PROs to use in assessing the quality of care.

Some observers are hopeful that once these data are available and when coupled with sophisticated analytic techniques, PRO data might be used in the coming years to better assess the:

- Risk of particular outcomes for patients with various clinical conditions, and
- Extent to which those outcomes are different from what would have been expected compared to the national experience for similar patients.

The data system under which the PROs will work not only permits the PROs to take advantage of a national data base for comparative studies, but also allows each case reviewed by the PROs to contribute to that national data base.

Medicare Beneficiary Health Status Registry

The Registry is a proposed longitudinal data base containing information formed by joining health status information obtained by a panel survey of beneficiaries and then linked with HCFA's administrative files. The survey will gather previously unavailable information regarding the health status of approximately 2 percent of the elderly as they enter the Medicare program and at 2 and 5 year intervals thereafter.

Goals

For the first time, there could be information about the health risks and conditions of each new Medicare cohort permitting better projection of needs. By enrolling successive cohorts over many years, changes in the health and utilization of new entering groups can be monitored over time. Through repeated survey contacts with the same individuals while they are Medicare beneficiaries, the progression of health and disease can be better measured, the relationship between the Medicare program and the health status of its beneficiaries can be more closely examined, and the effectiveness of specific health interventions relative to changes in health status can be better assessed. Specific goals of the Registry include:

(1) Measure the relationship of Medicare reimbursed services to the health status of Medicare beneficiaries;

(2) Describe, analyze, and understand health and disease (quality of life, well-being, functional status, and the prevalence, incidence, progression of illness and decline of health) longitudinally in successive cohorts of Medicare beneficiaries;

(3) Assess/evaluate the effectiveness, cost-effectiveness, and impact of specific medical and surgical interventions on health, quality of life, well-being, and functional status of Medicare beneficiaries;

(4) Monitor access to care in special populations;

(5) Provide a detailed sampling frame which can be used to select highly focused and efficient samples for studies of special sub-groups (e.g., minorities, ESRD beneficiaries, rural old, "old-old," and others) of the Registry sample; and

(6) Develop studies of cost and help develop more equitable payment adjustments for Health Maintenance Organizations,

Preferred Provider Organizations, and providers in rural areas.

Content

The Registry is proposed to collect information in five basic areas:

- Risk factors;
- Functional status;
- Sociodemographic variables;
- Medical history; and
- Quality of life.

Design/Development

The contract to develop and field test the data collection instrument was awarded to Research Triangle Institute in late 1990. Design and Field Test phases are each anticipated to require a minimum of 1 year. Implementation of the Registry may be as early as 1994, depending upon available funding, though trend data would not be available until the latter part of this decade.

During the Design Phase, the sampling approach and instrument will be refined and developed. Currently, the proposed design calls for a mailed questionnaire of slightly more than 40,000 Medicare beneficiaries, supplemented by telephone and in-person interviews. During the early years of the Registry, a smaller number of older beneficiaries, aged

70, 75, 80 and 85 will be added to the sample in order to provide cross-sectional information on current beneficiaries.

The Registry is being undertaken with joint support from AHCPR and HCFA. Subject to availability of funds, plans call for the survey to eventually include a 5 percent sample of Medicare beneficiaries. The Registry is currently being developed, but it will not be known for several years whether the Registry will be able to gather health status information of sufficient accuracy to satisfy the purpose for which it is being developed, or if so, at what cost. Therefore, no final decision has yet been made to implement the Health Status Registry.

Additional Data Sources

In addition, several other data sources are or will be available for monitoring changes as they relate to Medicare Part B services, and some notable examples should be mentioned in regard to the strategies and objectives discussed in this report.

Health Insurance Master File

This file provides two critical pieces of information: the date of death for all beneficiaries who die, and the demographics of the beneficiary population at risk, which is vital to epidemiologic studies of outcomes.

Project to Redesign Information Systems Management

Roughly contemporary with CWF efforts, HCFA is implementing methods for accessing and using its other and multiple sources of data, particularly claims-based data. PRISM is a major information resource management initiative to provide sophisticated electronic mechanisms to access and manipulate Medicare data more easily.

Chapter III

Measuring and Analyzing Changes in Utilization of Services

This chapter describes methodological issues in monitoring the growth in volume and intensity of Part B services[*] under Medicare, outlines a tracking approach that can provide further information as the OBRA 89 changes and subsequent changes are phased in, and summarizes several major research studies on growth in volume and intensity of services. As described in Chapter II, over the last few years HCFA has designed and has now begun to put in place a set of data acquisition and information management systems that will better support ongoing monitoring of the impacts of program changes on utilization, access, appropriateness, and outcomes of care. Nevertheless, even with improved data, formidable issues remain in identifying, measuring and analyzing these changes.

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[*] This report focuses on physician services paid for by Part B (Supplementary Medical Insurance) of Medicare. According to data compiled by HCFA's Bureau of Data Management and Strategy, Part B payments were $34.6 billion in 1989 ($24.8 billion in 1986); physician services accounted for $23.0 billion ($16.6 in 1986), outpatient hospital services for $5.9 billion ($5.0 in 1986), and independent labs for $1.1 billion ($0.70 in 1986). More detailed information can be found in Table Q-14 of the Social Security _Bulletin_, Volume 53, Number 12, December 1990.

Major Issues

There are obvious and important questions about the impact of the OBRA 89 changes on utilization of services; these include:

- What will happen to overall volume of services?
- What will happen to volume of specific types of services, such as primary care versus surgical procedures?
  - Will the use of services for which payments are increased (such as visits and consultations) or decreased (such as specialized technical procedures) show a response to the increase or decrease in Medicare payments and limits on balance billing?
  - Will changes in payment and balance billing/coinsurance patterns across specialties and geographic areas (e.g., States, urban and rural areas) result in changes in utilization patterns?
- What will happen to the volume and mix of services in areas that experience the largest increases or decreases in Medicare payments and/or balance billing/coinsurance amounts?
- What will happen to utilization of services in the

aggregate and for specific types of services, for special population groups (e.g., more elderly beneficiaries, disabled or ESRD beneficiaries, minorities)?

- Will the overall levels in use (and cost) of services increase, decrease, or remain unchanged as the statutory changes are implemented?

Longer Term

Beyond observing these specific but straightforward statistical trends, there are a set of longer-range research issues, such as:

- To what extent does procedure growth reflect demand factors such as patient needs and preferences, and to what extent does growth reflect supply factors such as physician availability and presence of facilities?
- How do physicians and patients change their behavior, both in the short and in the long run, in response to changes in payments and liabilities? For example, will beneficiaries' use of services change when their out-of-pocket costs are reduced by balance billing limits?
- What are the growth cycles of different kinds of procedures? Do some procedures have a self-limited cycle of growth (e.g., are used only in limited, well-defined circumstances)?

- To what extent is growth in services medically appropriate? Increases in levels of services may be appropriate, for example, if they represent new and clearly beneficial technology; increases could also represent proliferation of services whose effectiveness is uncertain.

Analytic Framework

In the past, because of data limitations, the Department has measured aggregate growth in utilization as a residual after subtracting or "netting out" two components from overall growth in outlays: (a) the part of growth that appears to be attributable to increase in the number of beneficiaries, and (b) the part of growth that appears to be attributable to adjustments for inflation. The remaining "residual" roughly represents increase in the volume and intensity of services per beneficiary. However, this approach gives no information as to the composition of the growth in services.

The development of new data systems promises more timely and more detailed identification and tracking of changes in levels of use and patterns of care. Similarly, more sophisticated analyses that build upon descriptive statistics should be possible. However, even with improved data, major conceptual problems remain in making comparisons over time and interpreting patterns.

Identifying Patterns and Trends

Over the next several years, new data sources and systems (described in more detail in Chapter II) can begin to allow more complete and more timely information on beneficiaries, services, and provider behavior. Descriptive statistics can be used to identify, observe, and track utilization trends and potential changes in patterns of care that may signal important implications for policy. The Department plans to monitor trends and patterns in utilization in the aggregate, but also for:

- Various types of services and procedures -- in different settings and across geographic areas (e.g., State, urban and rural areas),
- Areas or procedures that experience the largest changes in Medicare payments and/or beneficiary balance billing/coinsurance,
- Beneficiary characteristics (e.g., age, sex, race, disability/ESRD status), and
- Provider characteristics (e.g., specialty).

Future reports might present, for example, annual utilization statistics and tabulations across three potentially significant dimensions: population (beneficiaries), providers, and procedures.

Population/Beneficiary Characteristics. Regarding geographic areas and populations, the statement of managers for

OBRA 89 suggests that the Secretary monitor "services by State, [and] utilization of services in health manpower shortage areas."[2] Further analysis of groups of beneficiaries might yield some insight into factors that drive use of care, access barriers, and whether types of services are concentrated in some way. For example, utilization data could be developed for populations of special interest, such as beneficiaries in rural areas, minorities, and the disabled and ESRD beneficiaries.

Providers. Examination of the experience of individual providers and groups of providers is one approach to better understanding providers' behavioral responses to changes in payments. Analysis might also clarify whether changes in utilization occur generally or whether they are attributable to small groups of providers or unusual practice patterns.

Procedures. Regarding procedures, the OBRA 89 statement of managers suggests that monitoring should track "surgical procedures, nonsurgical procedures, emergency services, mental health services, specific frequently performed services, specific services for which medical practice guidelines are available,... and other categories or specific services the Secretary determines appropriate." Monitoring and specifying trends in use of individual procedures can portray (albeit retrospectively) the life cycle of procedures, and perhaps identify in a very preliminary way specific procedures for which utilization review may be warranted after further study.

Interpreting Patterns and Trends

Measuring change in use of services requires measurements that are consistent over time in order to distinguish change in services rendered from change in the claims processing and reporting systems. This distinction is especially difficult because the data systems that record Part B services have been (and continue to be) evolving and improving rapidly over the past decade; for example:

- This year (1991) will be the first complete year under the NCH data file described in Chapter II; thus comparisons to prior years will be incomplete;
- The MFS will not be implemented until 1992. Thus, changes and impacts deriving from the fee schedule are unlikely to be available until the 1993 Annual Report, and sketchy then;
- HCFA will attempt to examine the impact of the 1991 Medicare payment reductions (from OBRA 90) and 1991 balance billing limits. However, the phase-in of the NCH will make national comparisons problematic.

Over the longer term, questions posed in the first section of this chapter might point to development of not only aggregate utilization and trends, but also closer examination of patterns relating to utilization by characteristics of beneficiaries, types of services and procedures, and by characteristics of providers.

Issues in Monitoring and Interpretation

Linking theory and concepts of utilization, development of meaningful measures, and availability of timely data are key to any examination or strategy in monitoring and interpreting change. HCFA and the Department have made enormous progress over the last decade and continue to improve and refine data measures and collection activities given available information technology; not surprisingly, however, obstacles remain.

Continuous refinements in the data system, for example, eliminate previous sources of error but also disrupt the time series that are necessary for measuring change. More specifically, standardization of definitions of surgical global fees and reducing the use of local codes and modifiers are examples of data elements that will change and, in turn, create apparent changes in medical practices that are entirely data artifact. Adjustment for many of these discontinuities is theoretically possible, but both identification and correction are labor-intensive and may not be practical or possible under current budgetary constraints.

A second obstacle relates to the fact that there are approximately 7,000 HCPCS codes for medical procedures and thousands more when modifiers are counted. Thus, a table that simply presented changes in the use of each possible procedure code over time would be overwhelming. However, because relatively few codes are used by physicians for most care for

Medicare beneficiaries (e.g., the 100 codes most often used by physicians account for about 70 percent of all charge experience), consolidation is possible and can be useful. Additional ways of consolidating counts of procedures to make them more interpretable include use of:

- Relative value scales -- the resource-based or charge-based relative value scale could be used;
- Functional categories -- treating various functional categories such as office visits as a related set could provide some initial identification of utilization shifts toward visits.
- Clinical categories -- analysis of certain services which have related clinical purposes, or which may serve as substitutes for one another (e.g., a kidney stone may be treated through open surgery, extracorporeal shock-wave lithotripsy, or endoscopic removal) could provide insight on changes in use of any of these services.

HCFA is conducting intramural research and supporting extramural research to develop better analytic categories.

Ultimately attributing changes to causes, however, will be a complex task. An important goal of the analyses mandated by OBRA 89 is clearly determining the effects of program changes. Attributing changes in utilization to specific program changes will be difficult, though, for at least two reasons:

(1) Timeframes. Although it is easy to identify the moment

when a Medicare program change becomes operational, identifying the time at which it affects patient and physician behavior may prove much more difficult. For example, many of the payment changes under the MFS actually started with "overpriced procedure" cuts in OBRA 87 and OBRA 88 and will be phased in during a transition period extending into the mid-1990s. Conversely, physicians may respond to expected changes rather than reacting on the day changes occur; in extreme cases, the actual change may fall short of the expectation and the response to the actual change may be the reverse of that expected.

(2) Multiple and Concurrent Changes. The world of Part B services is changing in many ways at once, and disentangling causes will be, at best, very difficult. Although changes will be different for different groups of physicians and payments, making multivariate analysis possible, a very large number of possibly causal events will be occurring at roughly the same time, including:

- Within Medicare, the MFS, MVPS, and balance-billing limits;
- In the general health care sector, changes in the relations of physicians to hospitals, shifts in the policies of other insurers, and developments in health care technology;
- In the general economy, changes in the ability of beneficiaries to pay out-of-pocket costs and of

physicians to do without Medicare income.

Thus, despite the importance of the issues, causal conclusions may be difficult to establish.

Current Research

There are several major HCFA-funded studies in progress on changes in utilization of Medicare services in recent years. Final reports on these studies may be available by late 1991, but only preliminary findings are available at the time of writing. We will therefore report only illustrative examples of the preliminary results available. Preliminary results further highlight a number of methodologic and data limitations that emerge in the course of analysis.

Growth in Physician Services: (Laguna Research Associates, Nelda McCall, principal investigator). This study examines growth in physician services from 1986 to 1988, principally through analysis of the BMAD procedure file but with some analysis of the BMAD provider file. McCall and colleagues also used an expansion of the Florida relative value scale to consolidate counts of different types of procedures. Concerning data they found that:

- Large intra-State variations in provider data over time which suggests the provider file does not represent a consistent sampling pattern from 1986 to 1988, and therefore cannot be used to describe changes in services rendered by typical providers during that period.

- Large variations among carriers in use of modifiers and local codes makes consolidation of data across States very difficult for many categories of service.

Nevertheless, McCall was able to show some striking patterns that may hold up for the final report;

- Growth in services per beneficiary and in allowed charges vary so widely among carriers that generalizations seem very risky. From 1986 to 1988, among the 10 largest carriers, growth in services per beneficiary ranged from -5.8 percent in Pennsylvania to +49.6 percent in Florida, while growth in allowed charges ranged from 8.6 percent in Pennsylvania to 58.2 percent in Florida.
- For each of 4 major categories of service (medical, surgical, radiologic, and laboratory) about 20 procedures account for about half of services, half of allowed charges, and half of growth in outlays. (Thus, as already noted, indications for a limited number of procedures might be used to identify and monitor a large part of Medicare's cost and growth.)
- Increases in the average coded intensity of hospital and office visits (intensity creep) accounted for roughly a 1 percent increase in Medicare outlays over the 2 years; increases in payments for the same

services (inflation) and in number of visits (volume growth) accounted for about 10 times as much growth in outlays.

Utilization, Diffusion, and Substitution of High-Technology Procedures: (Health Economics Research, Janet Mitchell principal investigator). This study examines the use of three new high-tech procedures: percutaneous transluminal coronary angioplasty, magnetic resonance imaging, and extracorporeal shock wave lithotripsy (ESWL). Mitchell et al. describe the growth in use of these procedures, the diffusion of their use into different geographic and population groups, and the extent to which they complement or replace three established procedures (coronary artery bypass grafting, computerized axial tomography, and surgical removal of urinary stones). They studied the 1985-1988 period using data from the BMAD beneficiary file and from a file of all Medicare claims from 12 States.

Preliminary results indicate that:

- The newer procedures did not "replace" the older procedures as substitutes in the usual sense: rates for both new and old procedures grew throughout the period of study.
- The tendency of procedures to "plateau" in terms of utilization is quite variable. ESWL did plateau, but all other procedures, including surgical removal of stones, continued to grow.

- Procedures do "diffuse" in the sense that the percentage growth rate is higher in areas with initially low rates of use.
- Percentage differences between areas with initially low and high rates for a procedure tend to decrease with time.

Differences in utilization by sex and race also tend to decrease over time, but the decreases are not consistent.

Empirical Foundations of Physician Volume Performance Standards: (Urban Institute, John Holohan principal investigator). The purpose of this study was to establish better understanding of geographic variations in rates of growth in physician services in order to lay a foundation for possible State or regional volume-performance standards. The objective was to understand factors that influence these variations. Holohan and colleagues examined the BMAD procedure files from 1985 to 1988 and developed categories of clinically-related services in order to track the components of growth.

Only preliminary results are available from this study. They strongly confirm McCall's findings of wide differences in both spending rates and growth rates among carriers. The project will also examine factors that may predict or explain these varying rates, but even preliminary reports are not yet available.

Physician Response to Price Change: (Health Economics Research: Janet Mitchell, principal investigator). The purpose of this study is to analyze changes in the use of the OBRA 87 12 overpriced procedures. Specifically, three main analyses will be undertaken:

- Case studies for each of the overpriced procedures analyzing changes over the past few years in the diffusion of the technologies and in their clinical applications;
- Descriptive analysis of the utilization of the overpriced procedures from 1985 through 1989 (that is, both pre- and post- OBRA 87 legislation) using an 11-State 100 percent claims data base; and
- A descriptive analysis of trends in episodes-of-care at the beneficiary level; this analysis will attempt to identify changes in the provision of related medical/surgical services which the physician may alter in response to the fee reductions.

Preliminary results are not expected until late 1991 or early 1992.

Future Work

These preliminary results indicate clearly that substantial further work will be necessary in order to be confident of evidence on patterns of growth. Preliminary results are only suggestive of patterns of findings that might provide better understanding of how the use of medical services grows.

Substantial obstacles are apparent. At the most basic level, little is understood and conceptual models poorly developed regarding physicians and service mix, adoption of new technologies, and billing and income. Secondly, once theory is better developed, useful measures must be defined and data consistently collected to assess changes. These limitations clearly point to ongoing difficulties in sorting out issues of cause and effect.

Until basic research on effectiveness and physician behavior is advanced, activities over the next several years will focus on improving the reliability of current data elements, defining basic trends that lie behind the data, and developing a long-term research agenda for developing some improved evidence as to why growth is taking place.

Chapter IV

Measuring and Analyzing Changes in Access to Care

Access to health care can be defined as the lack of individual or system-related characteristics that pose barriers to receiving care. The concept of access is certainly not new, but the ability to define and measure it has been the topic of analysis and research for several decades -- with limited success. Several researchers have attempted to define access to care by modeling its various dimensions.

Major Issues

Despite efforts to more precisely define access and quantify its existence and impact on health status, OBRA 89 might have substantial impact on the access of Medicare beneficiaries to care. The potential effects, however, of OBRA 89 on access are complex and are extremely difficult to predict.

While access is a difficult concept to quantify (and correspondingly operationalize against) several measures might be considered initially. These include:

- The assignment rate/participation rate of physicians, and

- Beneficiary out-of-pocket expenses.

These are measures that relate to beneficiary financial ability to obtain care.

The monitoring of these measures coincides with a requirement under a separate charge of the OBRA 89 legislation. Section 1848(g)(6)(A) addition to the Social Security Act requires the Secretary to monitor:

> "(i) the actual charges on nonparticipating physicians for physician services furnished on or after January 1, 1991 under [Part B], and
>
> (ii) changes (by specialty, type of service, and geographic area) in (I) the proportion of expenditures for physician services provided under Part B by participating physicians, (II) the proportion of expenditures for such services for which payment is made under [Part B] on an assignment basis, and (III) the amounts charged above the recognized payment amounts under [Part B]."

The Department plans to monitor changes in access using (where applicable) these measures along with several important dimensions mentioned above by:

- Geographic area,
- Type of service,
- Characteristics of beneficiaries and areas where there is greatest change in fees and/or balance billing limits.

Predicting Physician Responses to Payment and Balance Billing Changes

The MFS will tend to increase payments for some kinds of services and decrease those for other kinds. The MFS will also generally increase payments in some geographic areas and decrease them in others. In addition, the MFS changes the amount physicians may bill the patient when assignment is not accepted. OBRA 89 limits balance billings for nonparticipating providers to 125 percent,[*] 120 percent, and 115 percent of Medicare fees in 1991, 1992, and 1993 respectively.

Available evidence regarding responses of providers to these changes is limited for the most part to responses in decreases in fees and/or balance billings, and is limited further by problems of underlying theory related to physician behavior and goals.[3] For example, there is disagreement whether increases in payments for visits will lead to a greater number of visits or more time with each patient per visit. Predictions of response are further complicated because the short-run response may be very different from the long-run response (for example, physicians in a surgical specialty would work harder to offset decreases in payments in the short run, but fewer physicians might enter the specialty in the long run).

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[*] There is one exception. Under OBRA 90 legislation, the limit was established as 140 percent for evaluation and management services.

Similarly, the changes in payment levels may change physician behaviors of accepting assignment or enrollment as a participating physician. Physicians do not accept Medicare's allowed charge as full payment on about 20 percent of bills and bill patients for the balance of their charge. Physicians might respond to the new limits in combination with fee changes either by accepting assignment (thus making care more accessible) or by avoiding Medicare patients (creating an access barrier). For example, will changes in effective payments, either related to fees or balance billing limits, discourage participation and assignment? Or correspondingly, will the competition within specific specialties or the relative share of Medicare patients (e.g., ophthalmology) counterbalance any incentives to provide care to fewer Medicare beneficiaries?

Predicting Beneficiary Responses to Payment and Balance Billing Changes

The response to changes in Medicare fees and balance billing limits on the part of beneficiaries is equally difficult to predict. Balance billing limits will lower beneficiary out-of-pocket expenses but increases in some fees (e.g., office visits) would also raise beneficiary coinsurance. While the former could increase access to services, the latter could also discourage access to care.

There is some limited evidence that use of services is inversely related to levels of out-of-pocket costs. By far the best study to date, however, was less than direct in its lessons for beneficiaries under the provisions of Physician Payment Reform. The Rand Health Insurance Study[4] indicated that increased cost sharing may discourage initial use of services, but did not necessarily change overall levels of service use or subsequent health status. However, the Rand study excluded Medicare beneficiaries.

Only about 20 percent of beneficiaries pay their coinsurance out of pocket. It is unclear whether changes in coinsurance will change the initial readiness of these beneficiaries to make office visits. Supply effects or even induced demand by providers due to increased fees must also be taken into account when attempting to assess changes.

About 75 percent of aged Medicare beneficiaries have supplemental private insurance.[5] This insurance is generally a "Medigap" policy that pays the Medicare deductible and coinsurance but less often covers balance billing. With the new limitations on balance billing, such billing becomes a more insurable risk, and many Medigap policies may expand to fill it. To the extent that this happens, Medigap premiums may rise while financial barriers to individual services fall; the overall impact on access to and use of care is (again) difficult to predict.

Measures of Access

In monitoring access to care the Department can use three different definitions of access. The first, and most straightforward, measures financial aspects surrounding access to care; this is discussed in some length above. The latter two are more tenuous in definition and ability to measure. The more traditional of these two focuses on the nature and prevalence of barriers to securing care; the second, which is more oriented to outcomes, focuses on whether beneficiaries receive medically necessary services. While important, both are longer term in usefulness for policy purposes.

Prevalence of Barriers

The proposed CBS (see Chapter II and discussion below) would provide the major source of information for directly examining the nature and prevalence of barriers to access. It would collect data on whether beneficiaries experience barriers while seeking care.

Necessary Care

The receipt of necessary care could be studied through a variety of analyses of claims data (see following section of this chapter), the use of the proposed Medicare Registry (see Chapter II), and through longer-term research (see following section). These approaches and processes may also provide limited and indirect evidence regarding access barriers. Monitoring of receipt of services defined by clinicians as "necessary" as part of the study of access to care can complement the study of the appropriateness of services rendered (described in Chapter V).

Access Measurement in the Current Beneficiary Survey

The CBS would provide the first assessment of access to care focused on the Medicare population. The first round of CBS would include the access series of questions (about providers and usual source of care), and further access questions would be asked of each respondent reporting a doctor, hospital outpatient, or emergency room visit. In addition, the Health Status and Functioning Supplement could contain questions that are related to and supportive of the access series. The access series and the Health Status and Functioning Supplement could be repeated each Fall.

Access Items. The access series would collect specific information on:

- Usual source of care: place and physician, including type of specialist;
- Barriers to care;
- Specific condition that necessitated care;
- Reasons for delaying or not obtaining care;
- Availability of physicians accepting assignment;
- Travel time to provider;

- Waiting time for an appointment;
- Waiting time in the office or clinic;
- Length of visit (time);
- General questions about beneficiaries perceptions of the Medicare program; and
- Satisfaction with the care provided.

Demographics and Measures of Need. The core questionnaire and the Health Status and Functioning Supplement would collect information that could be useful in analyzing the access of the elderly to health care. These include:

- Sociodemographic information: age, gender, race, education, and living arrangements;
- Financial information, including income;
- Insurance, including the availability of Medigap insurance;
- Perceived need for health care, including self-reported health status, reporting of selected chronic conditions, and reporting of restricted social role days;
- Utilization information, including number of beneficiaries with a visit, number of visits to emergency rooms, doctors, outpatient hospitals and hospitals, use of selected specialty and surgical services, and time elapsed since the last visit;
- Analysis of use by levels of care: primary, secondary and tertiary levels of care.

Clinically-Defined Necessary Services

Although claims data provide insufficient clinical detail to support strong inferences regarding access to care for individual episodes, carefully fitting together patterns of claims can provide signals about potential needs and actual services. Both cross-sectional and longitudinal studies of claims data can provide significant clues to possible access problems.

The Medicare Hospital Procedures Study

A straightforward example of analyzing claims data to provide inferences about access is the approach used in the hospital procedures analysis of the Medicare hospitalization data analysis.[6] This is a cross-sectional study using data on hospitalizations in 1986-87 to determine frequency of eight procedures for various age, geographic, and racial subpopulations of Medicare beneficiaries.

This study is only cross-sectional: it provides no information on trends. Nevertheless, it clearly demonstrates differences in levels of service for beneficiaries living in urban and rural areas and differences in frequencies of procedures for black and white beneficiaries. Taken by themselves, these data are not definitive: they do not adjust for possible differences in need and they reveal nothing about what level of service is correct for each procedure. Nevertheless, these studies do provide an important foundation for monitoring because it is possible to study whether such differences widen or narrow over time. For example, there would be reason for concern if introduction of the MFS were followed by widening of black-white differences or urban-rural differences; by contrast, if these differences narrowed after introduction of MFS there would be reason to believe that MFS had achieved some positive goals.

Cross-Sectional Variations in Utilization Rates

More recently, HCFA's Research Center at Project HOPE also recommended that observing disparities in utilization rates for various groups of beneficiaries at a point in time -- whether across geographic areas or across beneficiary characteristics such as race -- could be indicative of lack of access for the lower use groups as well as inappropriate overuse for the higher use groups.[7] Or, the underlying need for the service could vary for the groups, making it conceivable that each group is actually receiving the appropriate level of service even though the utilization rate is different for each group. There could even be some access problems within the higher use groups (e.g., lower access for inner-city residents combined with high utilization for other residents of the metropolitan area) and inappropriate utilization (either over- or under-use) among subpopulations of the low-use groups. While monitoring across-group variation in use rates will not reveal which of the above situations exists, it can nonetheless be quite helpful for determining which procedures appear to most warrant further investigation.

For example, HCFA could use Medicare Part B claims data to calculate age/sex-adjusted utilization rates for each individual procedure for selected geographic areas (e.g., States, urban vs. rural areas) and subgroups of the population (e.g., blacks vs. whites). For a given procedure, these utilization rates would then be compared across a type of geographic area or population subgroups to determine the extent of use variation for that procedure. In cases of more than two observations, the coefficient of variation (CV) could be computed to provide more information on the actual distribution of utilization rates. Algorithms could be developed to identify any procedure having a range or a CV above a prespecified threshold. High variation procedures identified could then be studied in more detail in an effort to better understand the reason(s) behind the variation. This might be an especially important approach for monitoring changes by area or types of procedures where the biggest changes in fees and/or balance billing limits are experienced.

Access Measurement in the Proposed Medicare Registry

As noted above, currently available Medicare data do not allow us to explain many of the differences in rates of hospitalization and procedures across different race, gender, and geographic strata. If access is one explanation, information collected initially and monitored longitudinally by the Registry could permit increased understanding of distribution of underlying differences in health status and risk factors for health conditions -- allowing a more direct link to measurement of need for health services.

Furthermore, these Registry data can be linked to Medicare utilization files. This will allow more direct comparison of differences in need with the use of services and identify possible groups with unequal access to care.

Beneficiaries in the Registry also might be followed to relate the treatment to which they have access with outcome and effectiveness of the intervention (see Chapter VI). That is, for those who do have access to services, does the quality of care differ and is there an effect on health status and outcomes? Is any variation related to specific geographic areas or subpopulations of beneficiaries?

Future Studies

Part of HCFA's research agenda in access to care is described in a forthcoming grant announcement. One approach for Medicare services is to identify those services that should be delivered (using available clinically-defined standards) and look for evidence as to whether they were delivered and, if not, why not. For example, the service may not have been delivered due to patient preferences rather than clinical or financial barriers.

Limitations. Methods used to define clinical standards for individual services are not yet precise for individual patients. Simple comparisons can be made across geographic areas and over time; controlling for unobserved sources of variation in these cases becomes more practical but less valid scientifically. Some epidemiologic techniques are better established for estimating needs for populations. But the "gold-standards" of good information, such as the larger, scientifically rigorous studies (e.g., National Institutes of Health-funded clinical trials) typically take several years and millions of dollars to design and undertake.

Overall, development of clear-cut evidence for programmatic purposes remains extremely problematic across several areas: defining and measuring changes in access, the reasons for change, and the development of rigorous scientific information for individual clinical indications.

Chapter V

Measuring and Analyzing Changes in Appropriateness of Care

There are three basic conceptual approaches to defining appropriateness: benefit-risk, benefit-cost, and implicit. Researchers define the benefit-risk approach in terms of expected health benefit (either mortality, morbidity, or psycho-social measures) exceeding expected negative consequences, while the benefit-cost approach adds consideration of resource costs. The implicit approach relies more on judgment without explicit definitions being delineated.[8]

Key to understanding the concept of appropriateness is the notion of expectation prior to the intervention, either on the part of the provider or the patient. More often than not, the effectiveness or outcome of an intervention is uncertain, but decisions must be made about management of a condition and course of care. Each of these three conceptual approaches, however, has limitations, and methods generally to measure appropriateness of individual interventions for individual patients are not yet precise and await refinement and empirical validation. Lastly, Wennberg's research on prostatectomy outcomes led to an important dimension that must be considered when measuring appropriateness -- patient preference.[9]

Major Issues

The MFS resulted, in part, from concern about incentives for inappropriate care in the traditional Medicare payment system. At the same time, the MFS raises fears it may create other incentives for inappropriate care.

Overpriced Services and Appropriateness

One of the forces behind the MFS was growing evidence that some procedures offered physicians payments for their time and training that were very high compared to other procedures -- that coronary surgery better reimbursed than office visits, and an endoscopy is associated with greater fees than a consultation. Critics saw these differences in payment as incentives for physicians to perform new, "high tech" procedures that had especially high fees relative to costs and pointed to the rapid growth rate for many well-reimbursed procedures as evidence that the incentives produced excessive growth.

There is, however, relatively little evidence to support the hypothesis that well-reimbursed procedures (those where historical payments are high compared to resource requirements) are more likely to be inappropriately performed than procedures where historical payments have been low compared to resource requirements. This is true for at least two reasons. For one, there is almost no evidence on the appropriateness of lower profit procedures such as office visits and consultations, so comparisons are impossible.

Second, agreement within the physician community on appropriate indications for procedures is only moderate, so that it is unclear whether physicians performing procedures for indications that other physicians judge inappropriate are motivated by disagreement or profit. For example, Park and colleagues at Rand[10] reported that their expert panels were unable to agree on the appropriateness of half of indications for angioplasty, coronary artery surgery, cholecystectomy, upper gastrointestinal endoscopy, colonoscopy, and carotid endarterectomy.

Appropriateness and Variation in Utilization

Rates for performance of procedures vary widely over small and large areas. While initial inclination is that a higher percentage of services would be inappropriate in localities where utilization is high, research to date has provided little support for this hypothesis.[11]

Physician Responses to OBRA 89 Changes

In discussing access and utilization in the last two chapters, it was noted that physicians facing reduced Medicare revenues under OBRA 89, as well as preceding and subsequent changes, might attempt to recover these losses. They might do so either by working harder and providing more services or by shifting their attention to other services or to non-Medicare patients. Either kind of response might produce a change in appropriateness, and the variety of possible responses makes tracking and analyzing appropriateness of care especially important.

Available Monitoring Data

The most important problems in monitoring appropriateness are defining appropriate care and collecting data to determine adherence to standards of appropriateness. The Medicare program approaches the question of appropriateness in two ways, through:

- National standards as to what services will be paid for (covered*) by the program, and
- More local programs of pre-certification, pre-payment screening, and post-service review.

Even though there are a few national rules governing what services will be reviewed under the latter activities, HCFA uses the professional judgment of local reviewers to make pre-certification or post-service determinations of appropriateness. Recently, a growing number of critics has pointed out that many accepted community practices have very limited scientific foundation, and judgments as to what is appropriate are usually difficult to justify through reference to the best scientific literature.[12,13]

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*Some services (such as most dental and preventive services) are excluded from coverage by law rather than because Medicare has determined them to be inappropriate.

Evidence on Appropriateness

A number of recent published studies have emphasized that substantial numbers of procedures are performed with either very poor documentation of positive reasons for performance or positive evidence of inappropriate reasons.[12,14,15] These studies are, however, cross-sectional, and collecting a second round of data to track trends would take as long or longer than the tracking system described below.

Carrier Activity

Although some claims for uncovered services are submitted and denied, counting denied claims for uncovered services is not an effective way of tracking appropriateness of care. Carriers also review the medical necessity of certain services (e.g., intermediate office visits, nursing home visits, comprehensive office visits, consultations) if the frequency exceeds preset thresholds, but these review decisions are made according to rules that vary from carrier to carrier and over time. Thus, tracking denial rates provides only very limited information as to the appropriateness of visit and consultation services.

Peer Review Organization Data

PROs review care, especially that provided in hospitals, and determine whether it is appropriate. The standards for these reviews can vary from PRO to PRO, and the centralized data are in summary form that cannot yield meaningful trend data. Chapter II of this report (as well as the fourth section of this chapter) describes the Department's plans for developing more systematic clinical guidelines for appropriate care and the way in which HCFA's PRO program will track adherence to these guidelines over the next 5-10 years.

Sources of Inappropriate Utilization

Theoretically, as monitoring systems begin to provide more concrete data on services, it will become more possible to identify patterns and reasons for inappropriate choices. Until that evidence becomes clearer, however, HCFA and the newly-created AHCPR will place emphasis on education of physicians and the public. PROs will target specific education to individual physicians and groups whose patterns of care appear inappropriate under PRO oversight.

Clinical Guidelines

The Department's lead agency for improving understanding and consensus on what care is appropriate and for facilitating the development and dissemination of clinical guidelines is

AHCPR. In addition, public and private organizations, especially professional groups, are vigorously engaged in developing clinical guidelines that will serve the same goal.

Agency for Health Care Policy and Research

Congress created AHCPR in 1989 to "enhance the quality, appropriateness, and effectiveness of health care services and access to such services" (OBRA 89). Through medical effectiveness research, facilitation of development of clinical guidelines, and dissemination of research findings and guidelines, AHCPR will increase the appropriateness of health care. This effort will make a contribution, along with the efforts of professional groups and others, to understanding what constitutes appropriate care. The result will be more informed clinical decisionmaking.

AHCPR's legislation authorizes development of guidelines both through panels convened by AHCPR and through contracts to public and nonprofit private organizations. The agency currently is convening panels and emphasizing that guidelines must be explicit and based on available knowledge. Guideline development supported by AHCPR requires that all scientific evidence be considered, the consequences of different options be weighed, and the scientific evidence and subjective judgments supporting the chosen options be described explicitly. The methodology emphasizes the importance of comprehensive evaluation of empirical evidence of effectiveness and all significant outcomes, benefits, and harms and emphasizes explicit documentation of methods, rationale, and assumptions.

AHCPR appoints panel members from among those recommended by panel chairs. Members represent a broad range of interested individuals and organizations, including physicians representing specialty and general practices, nurses, allied health, and other health care practitioners as well as consumers with experience or information pertinent to the guideline being developed.

AHCPR has convened panels to develop guidelines on:

(1) Visual impairment due to cataracts in the aging eye,

(2) Diagnosis and treatment of benign prostatic hyperplasia,

(3) Pain management,

(4) Diagnosis and treatment of depressed outpatients in primary care settings,

(5) Delivery of comprehensive care in sickle cell disease,

(6) Prediction, prevention, and early treatment of pressure sores in adults, and

(7) Urinary incontinence in the adult.

Guidelines for three conditions should be available in late 1991. These will then undergo a 2-year period of dissemination, review and evaluation. The other four guidelines should be completed in draft form sometime in 1991. AHCPR has also convened a guidelines panel on AIDS.

Non-Governmental Sources of Guidelines

The two most important nongovernmental groups sources of guidelines on appropriateness of care are physician groups and third party payers.

Physician Groups. In recent years, medical professional societies have become intensively involved in developing guidelines. In 1989 the American Medical Association's Office of Quality Assurance listed hundreds of practice guidelines, practice standards, and technology assessments, primarily developed by specialty groups.[16] That office's August 1990 newsletter carried announcements by professional groups of intention to develop more than 100 new guidelines.[17]

Third Party Payers. Many third party payers have used coverage guidelines to define the services for which they will pay. More recently, however, third parties have tried to develop clinical review guidelines through which they can determine whether a particular course of care, ranging from surgical intervention to psychiatric treatment, is reimbursable. Although third parties sometimes refer to these guidelines simply as coverage rules (avoiding any explicit statement about appropriateness), explicit statements about appropriateness are becoming increasingly frequent in third party decisions.

Evaluation of Alternative Sources. From the perspective of public policy, practice guidelines coming from both professional societies and third parties have serious limitations. Professional societies are membership organizations and may have difficulty in promulgating guidelines that either are inconsistent with their members preconceptions or would reduce the activities by which their members make a living. Thus, there is a fear that professional societies will identify as appropriate many practices that are, at best, marginal. Correspondingly, there is concern that specialty groups may develop guidelines useful for specialists but not for primary care physicians, nurses, and other health care personnel.

On the other hand, third parties have a fiduciary responsibility to minimize outlays and are almost always more directly accountable to those who pay the premiums than to the patients who receive services. Thus, there is also an understandable fear that third parties will identify practices as marginal or inappropriate that are, in fact, appropriate. These concerns appear to have contributed to the legislative decisions to create AHCPR and to place it within the Department's Public Health Service rather than within HCFA.

Tracking Changes in Appropriateness

The Department's lead for assessing appropriateness of care under Medicare is HSQB, which operates the PRO program. HSQB is engaged in a number of efforts which are aimed at making the

PRO program more systematic in its assessment of the quality of health care received by the Medicare population.

Current Peer Review Organization Issues

A number of critics of the current PRO program have alleged it to be "resource intensive," "unsystematic," "highly variable," "judgmental," and "of uncertain value." PROs currently review a sample of individual cases, primarily hospitalizations, for the purpose of making a determination about whether the care was, for example, reasonable, necessary, timely, adequate, complete, appropriate, and delivered in the most appropriate setting. The tools used by PROs to arrive at these decisions are limited to some extent by the judgment and experience of the individual physicians and nurses reviewing the case. Because individual experience and knowledge vary, the results of the review will vary. In addition, because the review focuses on a sample of cases, this approach can have a sentinel effect, but not always provide an opportunity for broad-based education and prevention of poor quality care.

Approach to Issues

HSQB has undertaken a program to address concerns with the current process by creating in the PROs the capacity to analyze all care (provided to a sample of beneficiaries) in ways which focus on the outcomes of care. The objective is to equip the PROs with skills and tools that will enable them to characterize patterns of use and patterns of outcome in their jurisdictions and to draw inferences about the performance of providers of medical services.

Peer Review Organization Structure and Skills. To perform these functions, PROs need both a suitable data management infrastructure and the epidemiologic and biostatistical skills to make effective use of the data. As a result, HSQB is proceeding simultaneously to:

- Make the current system more systematic and consistent, and
- Develop the data systems and epidemiologic tools to shift the PROs from a system of individual case review to one based on analyses of patterns of use and outcomes.

HSQB plans to address these complementary and sequential objectives through a combination of automated clinical patient data and an expert system of electronic clinical logic. Initially the automated data might be limited to that obtained from inpatient hospital medical records and the expert system will rest on consensus-based algorithms. In the longer term, the data required could include information from all care settings and the expert system could evolve into a real-time experience-based decision support tool founded on epidemiologic analysis of the experience of physicians treating Medicare patients.

Assumptions. The analytic framework for future PRO work is based on the premise that variation in patient management and treatment decisions, and in the outcomes of those decisions, results more from uncertainty about how best to care for patients than from individual culpable errors. PROs would therefore shift their focus from examining individual cases out of context to studying patterns of use and outcome in the context of the national, State, and local experience and trends. Such an approach could involve two directions of analysis and two kinds of data:

- Analytic directions -- PROs would need to monitor both geographic variations and time trends. Monitoring geographic variations involves both comparing their jurisdiction with the rest of the nation and comparing localities within their jurisdiction. Monitoring time trends ideally involves a more continuous monitoring system that can detect trends as they emerge rather than long after they have become established.
- Data sources -- PROs would monitor using both billing data, which are currently available but require further development for analysis, and an expanded data base (including the UCDS), discussed in more detail in Chapter II) that contains a broad range of clinical information from hospital and other patient records.

Epidemiologic Methods. The analytic techniques used in this work attempt to assess the risk of particular outcomes for patients with various clinical conditions and also the extent to which those outcomes are different from what would have been expected compared to the national experience for similar patients. Outcomes might be analyzed using survival models that focus on short- and long-term outcomes as well as the extent to which the risks of those outcomes change over time.

A variety of "hard" and "soft" outcomes could be analyzed including, mortality, morbidity (readmission to the hospital, length of stay, use of nonhospital ambulatory services), disability (skilled nursing facility and home health agency services) and expenditures. Other outcome measures can be developed over time, but the above measures are more readily available from existing Medicare data systems.

Case Example. Monitoring might show that the 30-day mortality rate for Medicare patients who had undergone bypass surgery varied widely within the PRO's jurisdiction. Using a combination of provided billing data, UCDS data, and possibly additional appropriate sampling, the PRO would determine whether the variation could be attributed to differences in risk for patients coming to surgery. Further, it could identify factors other than patient risk associated with higher mortality rates. If hospital-specific factors appeared to be involved, it could examine outcomes of other care provided at the high-rate hospitals. If certain practices appeared to be associated with higher rates the PRO could examine their association with higher rates in other settings and for other conditions.

Expected Impact

The system described here could significantly improve HCFA's ability over the next decade both to monitor and improve the quality of care delivered to Medicare beneficiaries and to track the impact of program changes closely.

Monitoring and Improving Care. HCFA would be able to measure the impact of treatment options on the health outcomes of patients by identifying those instances where outcomes obtained by various interventions are substantially different from what would have been expected given the characteristics of the patients. This might help contribute to understanding of which treatment interventions produce appropriate outcomes, and to provide evidence on the appropriateness of services that was based on outcomes rather than opinion. The agency could use this information to incorporate this into coverage guidelines or target consistent outliers (i.e., identify providers of poor care), instead of engaging in a case-by-case search for bad care.

Program Monitoring. The data system under which the PROs would work not only permits the PROs to take advantage of a national data base for comparative studies but also allows each case reviewed by the PROs to contribute to that national data base. The data base could be, in turn, very rapidly available to assess trends in the appropriateness of care delivered to Medicare beneficiaries.

Expected Resources

The cost of the new PRO review method is not expected to exceed the cost of the current PRO program. As the conversions are made, the funds previously allocated to the existing PRO review would be shifted to support the new type of review. There could be, however, the need for significant changes in both the PROs and HSQB:

- Greater expertise with regard to medical epidemiologists, biostatisticians, and health services researchers.
- Both groups will need the capacity to modify and refine the expert systems and decision support tools as new information emerges. To what extent systems will lag behind in incorporating new information is not clear.
- Finally, PROs will need to develop skills not only in conducting the analysis, but also in organizing the results in ways which incorporate them for policymaking as well as facilitate discussion with the medical community. PROs will need not only good scientific information which will withstand medical community scrutiny, but also the mechanisms and credibility in the community to present the analytic results in ways which foster appropriate changes in provider behavior.

Current Schedule

In early to mid-calendar year of 1991, HSQB plans to modify the contracts of seven PROs to begin implementation of phase I of the transition to a new set of PRO functions. These seven PROs will be capturing, in automated formats, complete clinical information for a 6 percent sample of hospital admissions in their respective States. The automated expert system will identify cases needing further physician review. This process will become the basis for PRO review. Depending upon these "pilot" results, other PRO contracts could be modified to conduct review in this way.

Simultaneously, HSQB could develop a prototype data management and analysis infrastructure -- including both hardware and epidemiologic software -- for PROs to use in performing the more sophisticated analyses of variations in use and outcome. All of the clinical data used in the first phase of the transition, and the automated patient information from the hospital record, will be retained and merged with other HCFA data for PROs to use in assessing the quality of care.

It will be at least 3 years before the results of infrastructure development efforts will be available. The first full year of automated data and logic for the first PROs will be available for use in the broad epidemiologic oversight program no earlier than 1994, and the second full year, which is necessary for measuring changes, in 1995. Thus, if all goes according to current plan, the first reports on meaningful trends in appropriateness (i.e., more than 1 year of changes) can be expected in the latter part of the decade.

Beyond this period, HSQB expects to extend conversion of the PRO program from a system that simply conducts more standardized consensus-based review of samples of cases to one based on epidemiologic analysis of patterns of use and outcome.

Timeliness of Peer Review Organization Data. The data to be tracked flow directly from an automated system used to screen cases for physician review. Thus, the availability of data depends on when a service is identified for abstraction, and how soon the record is abstracted after identification. Although it is premature to estimate this time period precisely, data are likely to be available for analysis 4 to 8 months after care is rendered. As is true with access data from CBS, these preliminary data will be subject to adjustment and correction, particularly based on physician reviews of records. Nevertheless, the screening data could provide epidemiologically meaningful data on underlying trends in appropriateness.

Chapter VI

Analyzing and Monitoring Outcomes

The four preceding chapters have described monitoring processes for utilization, access, and appropriateness, and the data systems that will support that monitoring. This chapter discusses and examines an added dimension: the analysis and monitoring of outcomes. It also contrasts monitoring with more traditional evaluations, taking as an example the evaluation of outcomes of care under PPS, and discusses the problems of drawing conclusions from monitoring. The final section briefly considers integrating the data systems discussed in this report, and using these in developing monitoring systems as steps toward realizing a continuous quality improvement program for Medicare.

Outcomes Analysis

Good health outcomes are the goal of health care and thus of any system that pays for health care. In using changes in health outcomes to assess changes in health care delivered to Medicare beneficiaries we must be able to measure consistently and reliably both changes in outcomes and any concurrent changes in the beneficiary population at risk. In addition, it is important, although extremely difficult, to demonstrate that changes in risk-adjusted outcomes are related to the changes in appropriateness and accessibility of care or other features of the care rendered.

Defining and Tracking Outcomes

There are three important outcomes of care: functional status, need for care, and survival. Research has developed increasingly sophisticated approaches to examining these outcomes, and the following summary is illustrative rather than comprehensive.

Functional Status. Although clinical studies have included measures of functional status as a measure of outcomes, the possibility of collecting such information for epidemiologic surveillance of the Medicare program is a more recent development. Wennberg and colleagues [18,19,20] collected functional status information from a group of Medicare beneficiaries to supplement a claims analysis, and more recently Elwood [21] has proposed more systematic collection for health care systems and has started the development of functional outcomes instruments. In 1990, with support from AHCPR, HCFA awarded a contract to the University of Minnesota to study outcomes of specific procedures in a representative sample of Medicare beneficiaries. This study will initially address three procedures with the possibility of extension to three more procedures a year on a regular basis.

Follow-up Care. In 1990 HCFA's Office of Research and Demonstrations released a study of hospital readmissions following eight procedures (total hip replacement, total knee replacement, repair of hip fracture, replacement of femoral head, cholecystectomy, partial excision of the large bowel, coronary artery bypass graft, and percutaneous transluminal coronary angioplasty) for Medicare patients receiving those procedures in 1986-7.[22] This study represents a pilot approach that has the potential to become a monitoring system for outcomes.

Survival. For 4 years, HCFA's HSQB has published information on mortality for Medicare beneficiaries following hospitalization at different hospitals.[23] The adjustment methods used for this study are generalizable to tracking trends for regions and subpopulations.

Sources of Outcomes Data

Chapter II reviewed several major sources of data; several of these are useful for outcomes analysis.

Claims Data. Although Chapter II focused on physician services that are identified in the NCH, the NCH also contains records for all hospital, nursing home, home health, hospital outpatient, durable medical equipment, laboratory services, and other services paid for by Medicare. Services provide information not only about care rendered but also about certain outcomes (for example, hospitalization for stroke or heart attack is an outcome for a hypertensive patient).

The Current Beneficiary Survey. The proposed CBS could provide much new data concerning risk factors such as demographics, income, perceived health status, and functional status, which can be linked to billing data.

The Peer Review Organization system. The PRO system now monitors a 3 percent random sample of hospital discharges that will be expanded to 6 percent starting in late 1991. The data collected from the PRO sample includes both risk factors and in-hospital outcomes of care.

The Health Insurance Master File. This file provides two critical pieces of information: the date of death for all beneficiaries who die, and the demographics of the beneficiary population at risk, which is vital to epidemiologic studies of outcomes.

The Medicare Beneficiary Health Status Registry. The Registry is a panel study now in the early stages of design work with joint support from AHCPR and HCFA. The goal is to include a 5 percent sample of Medicare beneficiaries. The survey would collect information on risk factors and functional status through interviews and track patients through the claims system. The Registry is currently being developed, but it will not be known for several years whether the Registry will be able to gather health status information of sufficient accuracy to satisfy the purpose for which it is being developed, or if so, at what cost. Therefore, no final decision has yet been made to implement the Health Status Registry.

Evaluations Vs. Continuous Monitoring

Even the best evaluations of Medicare program changes have been disappointing in three ways:

(1) Even when a major change can be clearly demonstrated, attributing change to a specific cause is very difficult. As with any "real-world" intervention or program change, evaluations must be carried out without adequate comparison groups and with situations whereby interventions occur only at one point in time. This means that it is difficult, if not impossible, to clearly delineate cause and effect changes, and to attribute changes specifically to the intervention under examination.

(2) The results are too often nonspecific and provide too little fine-grained detail to allow appropriate refinement of specific program features.

(3) The results have arrived so late that they are of little use for modifying the program. Program analysis therefore provides, at best, only general insights into the health care system.

A Pilot Evaluation Approach

One potential model for evaluating the impact of program change is the study of the impact of the Medicare hospital prospective payment system (PPS) on hospital care by Kahn, Brook, and colleagues at Rand [24,25] which was conducted under a cooperative agreement with HCFA's Office of Research. In this study the authors identified certain medical conditions whose hospital care was at high risk for an adverse impact on care under PPS. They then collected a sample of medical records for hospitalizations of Medicare patients with these conditions before PPS and another sample from patients in the same hospitals after PPS. They developed risk adjustment methods and both implicit and explicit measures of quality of care. They then demonstrated that patients whose care was good according to these measures had better risk-adjusted outcomes than patients whose care was poor. Finally, they compared both measured quality of care and risk-adjusted outcomes before and after the implementation of PPS. They found that quality of care for Medicare beneficiaries had shown a trend of improvement that was not interrupted by cost-containment measures during the first years of PPS.

As a model for monitoring, however, the Kahn-Brook study has five serious limitations:

(1) Timeliness. Almost 4 years passed from the discharge of the last patient in the study until the publication of results. Such time lags are inconsistent with using data for program management and refinement.

(2) Detail of results. Although the cost of the study was more than $5 million, the sample size was too small to associate

changes with specific features of program management that might be subject to adjustment or refinement.

(3) Episodic character. Administratively, the study design is more oriented to a single published product than to the continuous monitoring that is desirable for continuous program improvement.

(4) Ambiguous causation. Because PPS was introduced at the same time as the PRO system it was not possible to attribute changes to one cause or the other.

(5) Inpatient focus. An inpatient focus is highly appropriate for the PPS study of the effects of hospital payments, but extending the focus to outpatient services for other kinds of studies will be difficult. Inpatient records are much more complete and accessible than outpatient records, and UCDS will initially be an inpatient system only.

Thus, it is necessary to view this study more as a pilot that showed the feasibility of important strategies than as a model that only need be repeated to provide useful, timely information on program performance.

Future Directions

Integrating Information Systems

The data systems described in this report comprise the first step in developing an integrated information system for monitoring Medicare programs:

Complementarity -- Previous parts of this Report have described how these systems fit together to monitor a related set of measures of program performance.

Timeliness -- A second important common feature is the emphasis on more timely and continuous data. Table VI-1 provides estimates of the timeliness and routine availability of monitoring data in 1990 and 1995.

Ongoing Analysis -- Because data could be more available and on a more continuous basis, operational information should not have to depend on special studies. This more continuous availability is important to using data for ongoing program management.

Sampling Frames -- The BMAD beneficiary file, the CBS, the PRO random sample, and the proposed Medicare Beneficiary Health Status Registry have been designed in coordination to provide maximum sampling overlap. This will maximize the depth of data available. The Registry's proposed 5 percent sample is a subset of the PRO 10 percent sample, and the random component of the CBS sample is a subset of these samples.

Continuous Program Improvement

The monitoring systems described in the preceding chapters, as well as further systems described in this chapter, are designed to produce a more continuous flow of information in what systems architects call "real time" -- that is, sufficiently soon after systems changes are made and care is rendered to allow adjustment and fine tuning of the Medicare program.

Real time measures of performance are one of the key ingredients of continuous quality improvement -- the industrial engineering model of quality control that is receiving growing attention in the health care field. Developing such measures will continue to move HCFA toward being able to monitor and refine its program policies in the same way in which it and all beneficiaries expect health care providers to monitor and improve their performance.

Table VI-1

Change in Availability of Program Data: 1990-95

Information system	Typical lag (months)		Routine/ special study in 1990	In place
	1990	1995		
Part B utilization	10-22	5-8	routine	1991/2
Access to care	24-36	6-10	special	1993/4
Appropriateness of care	48	4-8	special	1994/5
Outcomes	12-36	6-12	largely special studies	1994/5

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